

**Principal Investigator: Ernest E. Moore, M.D.**

**COMIRB No: 16-0391**

**Version Date: 02/22/2019**

**Study Title: STAT (STatins and Aspirin in Trauma) Trial:** A Phase II, pragmatic, prospective, randomized, double-blind, adaptive clinical trial examining the efficacy of statins and aspirin in the reduction of venous thromboembolism in critically ill trauma patients.

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

**Why is this study being done?**

This study plans to learn more about whether giving two medications, rosuvastatin and aspirin, to injured patients can reduce the chance of that patient getting blood clots during recovery.

A severely injured trauma patient initially has bleeding due to the trauma. Once the bleeding is controlled, many victims of trauma become at high risk for developing clots inside their blood vessels. These include clots in major veins that can block the flow of blood, commonly known as deep venous thrombosis or "DVT", which can travel through the blood stream to the lungs and cause a very serious condition called pulmonary embolism. Small clots can also form in the lungs causing acute lung injury and acute respiratory distress syndrome, which may require the patient to be placed on a mechanical ventilator. This risk remains high for a long time following traumatic injury.

You are being asked to be in this research study because you were severely injured in a traumatic event and are at risk for complications related to blood clots. If you decide not to participate, your care will not be affected in any way.

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### **Other people in this study**

Up to 440 people from your area will participate in the study. This study is only being conducted locally, at this hospital

### **What happens if I join this study?**

If you join the study, you will be assigned randomly to one of two treatment groups. This study has two different groups of research subjects like you. To determine which group you will be in, we use a method of chance, called randomization, like a coin toss. You will be randomized to either: 1) the placebo group; or 2) the experimental group receiving rosuvastatin and aspirin.

You have an equal chance of being in either group. A placebo is a pill that looks like medicine but is not real. It will have no medical effect on you. If you are assigned to the experimental group, you will receive 20 milligrams of rosuvastatin and 325 milligrams of aspirin as soon as your doctor orders the standard-of-care medication to prevent the formation of blood clots. These amounts are the same as the FDA-approved doses used after open-heart surgery. You will receive these medications once a day while you are in the hospital and receiving standard of care medicines to prevent blood clots. Both of the medications used in this study have been approved for use by the U.S Food and Drug Administration (FDA) and are commonly prescribed by doctors to treat a number of medical problems. Rosuvastatin is most commonly used to treat high cholesterol and to prevent complications after heart surgery. Aspirin is routinely used to prevent blood clots in a number of clinical conditions. The use of these drugs to prevent blood clots after traumatic injury, however, is investigational.

You will not know which treatment group you are in. Neither will your study doctor. This information needs to be kept secret so that the study is based on scientific results, not on peoples' opinions. However, we can give this information out if you have an emergency.

Regardless of your participation in the study, or whether you are in the placebo or experimental group, your doctors will (if safe to do so) administer medications (such as the blood thinner, heparin) to try to prevent blood clots, according to the current standard of care.

If you are in an emergency, make sure you tell the emergency staff about this study. They can contact us, and we will give them all relevant information.

Blood samples will also be collected at 6, 12, 24, 48, 72, 120, and 168 hours after you were injured. The amount drawn for each sample is approximately 5 teaspoons, for a total of 35 teaspoons of blood for the entire study. We will try to collect these research blood samples at the same time hospital personnel collects blood for lab tests required for your treatment. These samples will be used to evaluate how your blood clots in

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response to your treatment using a special instrument called thrombelastography or "TEG".

72 hours after you start the study drug, you will receive an ultrasound examination of your legs and sites where intravenous lines had been placed (i.e. "I.V."s) to look for blood clots. These clots can form in the large veins of the legs or any other sites where an I.V. is placed. This is a painless examination using a special ultrasound device. If you are discharged from the hospital sooner than 72 hours after starting the study drug, you will not have the ultrasound performed.

The laboratory tests performed as part of the study are the same for both the placebo and experimental groups. The study continues until the study treatment is discontinued or 30 days post-injury, whichever is longer, and you can withdraw from the study at any time. If you decide to withdraw from the study, we will ask that you allow us to collect data from your chart, so we can understand how you responded to the treatments in the intensive care unit. You are not required to give us permission to look at your chart, and your treatment will not be affected in any way. Review of your chart will cover your records for up to 30 days after your enrollment into the study.

Additionally, we would like to keep your samples and data banked for future research use. This is optional, and you can request that your data and samples not be banked for unspecified future uses. If you change your mind in the future, you can at any time request that these data and samples be removed and destroyed.

### What are the possible discomforts or risks?

Discomforts you may experience while in this study include:

**Risk of study medications:** The risks of taking rosuvastatin are rare and include muscle pain, headache, abdominal pain, nausea, vomiting, muscle weakness, liver and kidney dysfunction as well as an injury to the muscles (called myopathy).

The risks of taking aspirin are uncommon and include heartburn, wheezing, gastritis (stomach irritation), ulcers in the gastrointestinal tract, bleeding from wounds or the stomach and intestines and allergic reaction.

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**Venipuncture risk:** In most cases, blood can be drawn from a line in your vein (I.V.) already placed as part of your standard medical care. In the event you do not have an I.V., blood will be drawn by placing a small needle in a vein in your arm to obtain blood samples (“venipuncture”). Blood is typically drawn this way if there is no I.V. Risks related with drawing blood from your arm include slight pain, bruising, lightheadedness, and a very low risk of infection. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin. We will make sure to try and obtain blood at the same time as hospital personnel gets blood for your treatment to avoid any extra venipunctures.

**Ultrasonography risk:** An ultrasound examination is a non-invasive imaging test that uses sound waves to make images of structures inside your body. During the test, the examiner will place a small amount of lubricating jelly on the skin followed by the ultrasound probe. You will not feel the sound waves and there should be no discomfort associated with the procedure.

**Risk of unplanned release of protected health information (PHI):** There is a risk that people outside of the study team will see your personal information. We take every precaution to protect your personal information, but it cannot be guaranteed.

The study may include risks that are unknown at this time.

### What are the possible benefits of the study?

This study is designed for the researcher to learn more about the use of the medications rosuvastatin and aspirin to prevent blood clots after traumatic injury. However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomforts or risks.

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### **Are there alternative treatments?**

There may be other ways of treating you to decrease the risk of blood clots after trauma. These other ways include heparin or other anticoagulants (blood thinners). These are routinely given to prevent blood clots in trauma, once the patient is safe from bleeding. Sometimes no preventative treatment is given, because it is either not safe or not needed. Whether you participate in the study or not, your doctor will decide whether these treatments are needed, independently from the study.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

### **Continuation in this study**

If you continue to be in the study, we will continue to watch you closely and record pertinent information during your hospital course for 30 days after your injury or until you leave the hospital. If you are discharged before 30 days after injury, we will contact you 30 days after your injury to see how you are doing.

### **Who is paying for this study?**

This research is not funded.

Dr. Ernest Moore and Dr. Hunter Moore, along with the University of Colorado Denver, have a financial interest in Thrombo Therapeutics, Inc., a company that holds licenses related to some of the assays used in this study. Please feel free to ask any further questions you may have about these matters.

### **Will I be paid for being in the study?**

You will not be paid to be in the study.

### **Will I have to pay for anything?**

It will not cost you anything to be in the study.

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### **Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

### **Can I be removed from this study?**

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

### **What happens if I am injured or hurt during the study?**

If you have an injury or adverse effect while you are enrolled in the study, you should call Ernest E. Moore, MD immediately. His phone number is 303-602-1820. We will arrange to get you medical care if you have an injury or adverse effect that is caused by this research. However, you or your insurance company will have to pay for that care.

### **Who do I call if I have questions?**

The researcher carrying out this study is Ernest E. Moore, MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Ernest E. Moore, MD at 303-602-1820. You will be given a copy of this form to keep.

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You may have questions about your rights as someone in this study. You can call Ernest E. Moore, MD with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

### **Optional Consent and Authorization for Data and Blood Banking for Future Research**

Dr. Ernest E. Moore would like to keep some of the data and some of the blood that is taken during the study but not used. If you agree, the data and blood will be kept and may be used in future research to learn more about trauma related illnesses. The research that is done with your data and blood is not designed to specifically help you. However, it might help people who have a traumatic injury in the future. Reports about research done with your data and blood will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and blood will not affect your care in any way.

The choice to let Dr. Moore keep the data and blood for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and blood can be kept for research, you can change your mind at any time. You can contact Dr. Moore to let him know that you do not want your data or blood used any longer and they will no longer be used for research. Otherwise, they may be kept until they are used up or until Dr. Moore decides to destroy them.

When your data and blood are given to other researchers in the future, Dr. Moore will not give them your name, address, phone number or any other information that will let the researchers know who you are.

Sometimes data and blood are used for genetic research (about diseases that are passed on in families). Even if your data and blood are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and blood will only be used for research and will not be sold. The research done with your data and blood may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your data and blood include learning more about what causes illnesses in trauma patients, how to prevent them and how to treat them. The greatest risk to you is the release of your private information. Dr. Moore will protect your records so that your name, address and phone number will be kept private. The Combined Biomedical Consent and Compound HIPAA authorization  
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chance that this information will be given to someone else is very small. There will be no cost to you for any data or blood collection and storage by Dr. Moore.

Please read each sentence below and think about your choice. After reading each sentence, check "yes" or "no." If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your data and blood, you may still take part in the study.

I give my permission for my data and blood to be stored in a central tissue bank at DHHA for future use by the study investigators:

1. I give my permission for my data and blood to be kept by Dr. Moore for use in future research to learn more about how to prevent, detect, or treat trauma-related illnesses.

Yes                       No                      \_\_\_\_\_ Initials

2. I give my permission for my data and blood to be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes).

Yes                       No                      \_\_\_\_\_ Initials

3. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

Yes                       No                      \_\_\_\_\_ Initials

### Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it. The institutions involved in this study include:

Denver Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

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We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

*Ernest E. Moore, MD  
777 Bannock St.  
MC 1655  
Denver, CO 80204  
(303) 602-1820*

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team
- The National Institutes of Health (NIH)
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- The members of the Data Safety Monitoring Board for this study

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

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### **Information about you that will be seen, collected, used and disclosed in this study:**

- Name and Demographic Information ( age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Blood and plasma samples and the data with the samples

### **What happens to Data, Tissue, Blood and Specimens that are collected in this study?**

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.

Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.

If data, tissue, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.

Any product or idea created by the researchers working on this study will not belong to you.

There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

### **HIPAA Authorization for Optional Additional Study Procedures**

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

Some of these optional procedures may involve genetic testing or the use of your genetic information. Your genetic information will not be released to others.

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If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

\_\_\_\_\_ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

\_\_\_\_\_ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

### Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Consent form explained by: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Investigator: \_\_\_\_\_

Investigator must sign within 30 days

Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Date \_\_\_\_\_

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Witness Print Name: \_\_\_\_\_

Witness of Signature

Witness of consent process

\_\_\_\_\_ Date \_\_\_\_\_

Legally Authorized Representative/  
Proxy Decision Maker

Print Name: \_\_\_\_\_